April 25, 2025

Guangzhou Daxin Health Technology Co., Ltd
% Cassie Lee
Official Correspondent
Share Info (Guangzhou) Medical Consultant Ltd.
No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road,
Huangpu District
Guangzhou, Guangdong 510700
China

Re: K243082
Trade/Device Name: Infrared Thermometer
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: Class II
Product Code: FLL
Dated: March 19, 2025
Received: March 24, 2025

Dear Cassie Lee:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Porsche Bennett

Porsche Bennett
For David Wolloscheck
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices, and
Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243082

Device Name
Infrared Thermometer

Indications for Use *(Describe)*

For T30:
The Infrared Thermometer is a non-sterile, reusable, handheld device. It is intended for measuring human body temperature for people of all ages by detecting infrared heat from the forehead and auditory canal. When measuring forehead temperature, it is non-contact and the distance of measurement is 1-3cm. The device can be used by consumers in homecare environment.
For TE-82:
The Infrared Thermometer is a non-sterile, reusable, handheld device. It is intended for measuring human body temperature for people of all ages by detecting infrared heat from the auditory canal. The device can be used by consumers in homecare environment.
For TE-102 and TE-79:
The Infrared Thermometer is a non-sterile, reusable, handheld device. It is intended for measuring human body temperature for people of all ages by detecting infrared heat from the forehead. When measuring forehead temperature, it is non-contact and the distance of measurement is 3-5cm. The device can be used by consumers in homecare environment.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary for K243082

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 801.92.

Prepared on: 4/25/2025

1. Submitter's Information

Sponsor Name: Guangzhou Daxin Health Technology Co., Ltd
Address: Room 810, No.1, Yichuang Street, Huangpu District, Guangzhou (China-Singapore Guangzhou Knowledge City) Guangdong
Post Code: 510700
Contact name: LuPeng Guo
Tel: +86 17324378052
E-mail: guolp@daxinhealth.com
Manufacturer Address: Room 601, Building 3, No. 9, Jinshagang Road 1, Dalang Town, Dongguan City Guangdong
D-U-N-S Number: 722481840

Application Correspondent:

Contact Person: Ms. Cassie Lee
Share Info (Guangzhou) Medical Consultant Ltd.
Address: No. 1919-1920, Building D3, Minjie Plaza, Shuixi Road, Huangpu District, Guangzhou, China
Tel: +86 20 8266 2446
Email: 382198657@qq.com

2. Subject Device Information:

Subject Device Information
Type of 510(k): Traditional
Device Name: Infrared Thermometer
Models: T30, TE-82, TE-79, TE-102
Classification Name: Clinical electronic thermometer.
Review Panel: General Hospital
Product Code: FLL
Regulation Number: 880.2910
Regulatory Class: II

3. Predicate Device Information

Predicate Device (K213011)
Sponsor: Bioland Technology Ltd
Trade Name: Infrared Thermometer
Model: E201

Device Classification Name: Thermometer, Electronic, Clinical
Common Name: Clinical electronic thermometer
Review Panel: General Hospital
Product Code: FLL
Regulation Number: 880.2910
Regulation Class: II

4. Device Description

The Infrared Thermometer is a non-sterile, reusable device. Infrared thermometer are handheld, battery-powered devices designed to measure body temperature by receiving infrared energy radiation from the ears or forehead. When measuring forehead temperature, it is non-contact. The device can be used by consumers in homecare environment. There are four models. T30, which can measure body temperature by receiving infrared energy from the forehead or ear canal. TE-82 measure body temperature by receiving infrared radiation from the ears; TE-79 and TE-102 can measure body temperature by receiving infrared energy radiation from the forehead.

The thermometer has the result of measurement through the forehead temperature mode or ear temperature mode directly displayed on the LED or LCD display.

The results of measurements can also be transferred to the APP via Bluetooth for recording and display

5. Intended Use / Indications for Use

For T30:

The Infrared Thermometer is a non-sterile, reusable, handheld device. It is intended for measuring human body temperature for people of all ages by detecting infrared heat from the forehead and auditory canal. When measuring forehead temperature, it is non-contact and the distance of measurement is 1-3cm. The device can be used by consumers in homecare environment.

For TE-82:

The Infrared Thermometer is a non-sterile, reusable, handheld device. It is intended for measuring human body temperature for people of all ages by detecting infrared heat from the auditory canal. The device can be used by consumers in homecare environment.

For TE-102 and TE-79:

The Infrared Thermometer is a non-sterile, reusable, handheld device. It is intended for measuring human body temperature for people of all ages by detecting infrared heat from the forehead. When measuring forehead temperature, it is non-contact and the distance of measurement is 3-5cm. The device can be used by consumers in homecare environment.

6. Comparison to predicate devices

Compare with the predicate devices, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between the subject device and predicate devices do not raise new questions of safety or effectiveness.

Elements of Comparison	Subject Device (K243082)	Predicate Device (K213011)	Verdict
Company	Guangzhou Daxin Health Technology Co., Ltd	Bioland Technology Ltd	—
Trade Name	Infrared Thermometer	Infrared Thermometer	—
Classification Name	Clinical electronic thermometer.	Clinical Electronic Thermometer	Same
510(k) Number	K243082	K213011	—
Product Code	FLL	FLL	Same
Thermometer Type	Infrared Forehead or Ear Canal Thermometer	Infrared Forehead or Ear Canal Thermometer	Same

Intended Use / Indications for Use	For T30: The Infrared Thermometer is a non-sterile, reusable, handheld device. It is intended for measuring human body temperature for people of all ages by detecting infrared heat from the forehead and auditory canal. When measuring forehead temperature, it is non-contact and the distance of measurement is 1-3cm. The device can be used by consumers in homecare environment. For TE-82: The Infrared Thermometer is a non-sterile, reusable, handheld device. It is intended for measuring human body temperature for people of all ages by detecting infrared heat from the auditory canal. The device can be used by consumers in homecare environment. For TE-102 and TE-79: The Infrared Thermometer is a non-sterile, reusable, handheld device. It is intended for measuring human body temperature for people of all ages by detecting infrared heat from the forehead. When measuring forehead temperature, it is non-contact and the distance of measurement is 3-5cm. The device can be used by consumers in homecare environment.	The Infrared Thermometer(model: E201) is a non-sterile, reusable, handheld device. It is intended for measuring human body temperature for people of all ages by detecting infrared heat from the forehead and auditory canal. When measuring forehead temperature, it is non-contact and the distance of measurement is 1~5cm. The device can be used by consumers in homecare environment.	Similar Note 2

Contact type	Non-contact/ Contact	Contact/Non-contact	Same
Rx/OTC	OTC	OTC	Same
Display resolution	0.1 °C /°F	0.1 °C /°F	Same
Sensor type	Thermopile	Thermopile	Same
Response time	1 s	1 s	Same
Operating Environment Condition	Temperature: 50°F~104°F (10°C~ 40 °C) Relative humidity: ≤85% RH	15~40 °C, RH≤85% (non-condense)	Same
Storage Environment Condition	Temperature: -4° F~131° F (-20~55°C) Relative humidity: ≤93% RH	-20~55°C, RH≤93% (non-condense)	Same
Intended patient	All kinds of patients (including adults / children / infants)	All kinds of patients (including adults / children / infants)	Same
Display	LCD/ LED Display	LCD Display	Different Note 5
Reference body site	Axillary	Axillary	Same
Measurement method	Infrared radiation detection	Infrared radiation detection	Same
Measurement mode	Forehead mode Ear mode	Forehead mode Auditory canal mode	Same
Measuring range	32.0°C ~43.0°C (89.6 °F~109.4°F)	32.0°C ~43.0°C (89.6 °F~109.4°F)	Same
C/F switchable	Yes	Yes	Same
Measuring accuracy	±0.4℉，96.8~102.2℉（±0.2℃，36.0~39.0℃），±0.5℉,86.9~96.7℉, 102.3~109.4℉(±0.3℃，32.0~35.9℃,39.1~43.0℃)	±0.3℃(32.0℃~34.9℃) ±0.2℃(35.0℃~42.0℃) ±0.3℃(42.1℃~43.0℃)	Different Note 1
Measurement distance	For forehead: T30: 1cm~3cm, TE-102 and TE-79: 3cm~5cm For ear: The tip of the probe was inserted into the external auditory canal.	Forehead mode:1-5 cm	Different Note 2

Memory	32 sets or 24 sets	32 sets	Different Note 3
Power source	2xAAA (1.5V), DC 3.0V	2xAAA (1.5V), DC 3.0V	Same
Signal transmission	BLE5.0	N/A	Different Note 4
Patient contact materials	ABS and PC	ABS	Different Note 6
Electric Safety and EMC	IEC 60601-1: 2020 IEC 60601-1-11 IEC 60601-1-2:2020	IEC 60601-1: 2005/A1; 2012 IEC 60601-1-2: 2014	Same
Performance	ISO 80601-2-56	ISO 80601-2-56	Same

Note 1:

The measurement range of subject device is different from the predicate device. The performance testing shows that the subject device complies with the performance standard ISO 80601-2-56. Therefore, this difference does not affect the performance and accuracy.

Note 2:

The measurement distance is different. But the Primary Predicate Device range covers the range of the subject device. So, the different does not raise different questions of safety and effectiveness.

Note 3:

The purpose of memory function is intended to store and view the previous measurement data. The function has been verified during software verification. The difference does not raise any issues on the device safety and effectiveness.

Note 4:

The Bluetooth version of subject device is different from the reference device. Compared with Bluetooth 4.0, Bluetooth 5.0 has improved in terms of transmission speed, coverage, energy consumption, multi-device connection, transmission distance and compatibility. The subject device complies with the performance standard FCC CFR Title 47 Part 15 Subpart c § 15.247. Therefore, this difference does not affect the performance and accuracy.

Note 5:

The subject device and predicate device display different screens. However, the subject device conforms to the requirements of IEC60601-1 standard, the display screen may be different, but it can still display information correctly, so this difference will not affect the performance and safety of the product.

Note 6:

Although the materials are slightly different, the materials of the subject device meet the requirements of the FDA's guidance document Use of International Standard Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1:

Evaluation and testing within a risk management process". Therefore, this difference does not affect the biocompatibility safety of the product.

Final Conclusion:
The subject device is substantially equivalent to the predicate device K213011.

7. Test Summary

7.1 non-clinical data

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- IEC 60601-1 2020-08 Edition 3.2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Note: This standard is recognized with relevant US national differences applied, see references #1 and #2 in the Relevant FDA Guidance and/or Supportive Publication section below.
- IEC 60601-1-11 Edition 2.1 2020-07 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance --Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used in the Home Healthcare Environment.
- IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- ISO80601-2-56 Medical electrical equipment Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature Measurement

- Software Verification and Validation Testing
  Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

- Biocompatibility Test
  The subject device is biocompatible for its intended use. They are complied with the FDA’s guidance document Use of International Standard Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

- Cybersecurity
  Cybersecurity software documentation was created for subject Infrared Thermometer device according to FDA guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices "issued on October 18.2018.

7.2 Summary of Accuracy repeatability verification

The testing is conducted pre ISO 80601-2-56 Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.

This performance test consists of a minimum of 150 subjects, divided into four groups: 0 up to 3 months, 3 months up to 1 year, older than 1year and younger than 5 years, and older than 5 years... The test result demonstrated the clinical performance of the subject device complied with the requirement of standard ISO 80601-2-56.

9. Final Conclusion

The subject device has met all established acceptance criteria for performance testing and design verification testing. Results of performance and biocompatibility testing conducted demonstrate that the subject device supports a substantial equivalence determination to the predicate device K213011.